IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES INC.; AND GALDERMA LABORATORIES, L.P., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. Defendant.	C.A. No. 09-184-LPS **PUBLIC VERSION**
MYLAN PHARMACEUTICALS, INC., Plaintiff, v. GALDERMA LABORATORIES INC.; GALDERMA LABORATORIES, L.P.; AND SUPERNUS PHARMACEUTICALS, INC. Defendants.	C.A. No. 10-892-LPS **PUBLIC VERSION**

DECLARATION OF PHILIP B. NELSON, PH.D., IN SUPPORT OF MYLAN PHARMACEUTICALS INC.'S OPENING POST TRIAL BRIEF REGARDING REMEDY

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DECLARATION OF PHILIP B. NELSON, PH.D.
IN SUPPORT OF MYLAN'S POST-TRIAL BRIEF REGARDING REMEDY

September 2, 2011

I, Philip B. Nelson, declare as follows:

I. INTRODUCTION AND ASSIGNMENT

1. My name is Philip B. Nelson. I am a Principal in the Washington, DC office of the consulting firm, Economists Incorporated.

2. I graduated with an A.B. degree from Dartmouth College in 1973. I received a Ph.D. in economics from Yale University in 1980. My areas of academic specialization included microeconomics and industrial organization, with applications to antitrust and regulation. I was the Assistant Director for Competition Analysis at the Federal Trade Commission. I have taught economics at Yale University and antitrust law at Fordham Law School. I am currently a vice chair of the American Bar Association Antitrust Section's Health Care and Pharmaceuticals Committee. I have worked as an expert on a number of matters involving pharmaceuticals and have testified in district court as an economic expert on pharmaceuticals and damage estimation. My hourly rate is $690. A copy of my curriculum vitae is attached as **Exhibit 1.**

3. I have been retained by Mylan Pharmaceuticals Inc. ("Mylan") to analyze several economic issues related to the sale of doxycycline delayed-release 40 mg capsules marketed by Galderma Laboratories Inc. and Galderma Laboratories, L.P. (collectively "Galderma") as Oracea® and the introduction of generic doxycycline delayed-release 40 mg capsules by Mylan, which are prescription pharmaceuticals used to treat rosacea (a chronic skin disease that is marked by redness of the face, flushing of the skin, and the presence of hard pimples (papules) or pus-filled pimples (pustules) and that may affect the eyes). I have been asked to evaluate: (a) whether Galderma has or will suffer an irreparable injury for which monetary damages are inadequate if a permanent injunction[1] is not issued; (b) the balance of hardships to Galderma and Mylan related to the potential granting of a permanent injunction; and (c) whether the public interest would be served by a permanent injunction.

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[1] I use the phrase "permanent injunction" to imply a "pure" permanent injunction that is not accompanied by other terms that go beyond the enjoining of entry, such as compensation to the enjoined party or an agreement that allows entry contingent on the payment of royalties.

4. I have previously submitted a declaration in conjunction with Mylan's opposition to a preliminary injunction. In addition, I have submitted an expert report, testified at deposition in this case, and attended the trial. During the course of my work in this litigation, I have reviewed a substantial amount of the evidence of record, including fact and expert testimony. In addition to the materials described above, cited in my reports, and/or identified during my prior testimony, I reviewed the Court's June 28, 2010 and August 26, 2011 Opinions and the recent declaration of Mylan's President, Mr. Mauro, in preparing this declaration.

II. BACKGROUND AND LEGAL STANDARDS

5. I understand that Mylan's ANDA No. 90-855 was filed in October 2008. I further understand that Mylan's ANDA was later amended to include a Paragraph IV certification in which Mylan certified that its product did not infringe any valid claims of U.S. Patent Nos. 7,211,267 (the "'267 patent"), 7,232,572 (the "'572 patent"), 5,789,395 (the "'395 patent"), and 5,919,775 (the "'775 patent"). I also understand that these patents were issued by the U.S. Patent Office prior to July 2010.

6. I understand that on June 28, 2010, the Court granted Galderma's request for a preliminary injunction based on the Court's finding that Galderma was likely to succeed in proving infringement of the '267 and '572 patents.

7. [redacted]

8. I understand that following a bench trial on the merits, on August 26, 2011, the Court issued an Order finding that Mylan does not infringe any of the asserted claims of the aforementioned patents, including the '267 and '572 patents on which the Court based the preliminary injunction.

9. I understand that U.S. Patent No. 7,749,532 (the "Chang patent") issued on July 6, 2010, after Mylan obtained FDA approval of its ANDA product. I further understand that

Mylan did not and was not required to file a Paragraph IV certification regarding the Chang patent.

10. [redacted]

11. [redacted]

12. I understand that on August 26, 2011, the Court found that Mylan infringed the asserted claims of the Chang patent, which was found to be valid.

13. With respect to permanent injunctions in patent cases, I understand that the party seeking a permanent injunction must establish four factors: (1) that it has suffered an irreparable injury; (2) that remedies available at law are inadequate to compensate for that injury; (3) that considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

14. Below, I analyze each of these factors and conclude that injunctive relief (in the form of a permanent injunction) is not necessary.

III. GALDERMA IS UNLIKELY TO SUFFER ANY IRREPARABLE INJURY FOR WHICH MONETARY DAMAGES ARE INADEQUATE

15. I have analyzed the first two of the four permanent injunction factors described above in determining whether a permanent injunction is appropriate together due to the overlapping issues. Specifically, I have analyzed whether Galderma is likely to suffer irreparable injury that cannot be compensated by monetary damages, in the event that a

permanent injunction against Mylan's product is not issued and Mylan launches its FDA-approved generic doxycycline product in the market.

16. While Galderma may lose sales revenue and market share to Mylan due to Mylan's market entry with a generic product, any alleged lost profits to Galderma can be assessed by means of typical damages methodologies. [redacted] Finally, Galderma's ability to mitigate damages through carrying out current life-cycle management strategies would also be assessed.

17. Oracea®'s pricing, sales and other market-based information would provide the inputs for such a damage calculation.

18. Appropriate compensation, such as a reasonable royalty, would be readily calculable in this case. Although I have not previously analyzed or opined on the proper amount of compensation, or the appropriate royalty for the Chang patent, I am prepared to do so at the Court's direction.

IV. THE BALANCE OF HARDSHIPS TO GALDERMA AND MYLAN WEIGHS AGAINST GRANTING A PERMANENT INJUNCTION

19. In analyzing the balance of hardships of granting a permanent injunction, as opposed to another form of remedy in this case, an economist would not only take into account the potential damages that Galderma would incur if there was entry by an unlicensed generic that violated valid patent rights, but also take into consideration [redacted]

20. More specifically, I understand that the Court found that Mylan's FDA-approved generic doxycycline product does not infringe the four patents. I also understand that the Court's findings regarding the '267, '572, '395 and '775 patents indicate that Oracea® is not a commercial embodiment of those patents, and that the Court determined the '395 and '775 patents to be invalid.

21. I understand that the '267, '572, '395, and '775 patents all issued well before July 2010.

22. Notwithstanding that Oracea was found not to embody any of those four patents and two of the four were found to be invalid, [redacted]

23. [redacted], weighing against a permanent injunction and suggesting that some other mechanism, such as a royalty arrangement, is more appropriate.

V. A PERMANENT INJUNCTION WOULD NOT SERVE THE PUBLIC INTEREST

24. There are several aspects of the public interest at stake in this matter. There is the public interest in preserving the exclusive rights afforded by the patent system. On the other hand, there is the public interest in encouraging generic entry into pharmaceuticals and achieving lower drug costs through increased generic competition. A permanent injunction would not serve the public interest because consumers would be denied, without compensation, the opportunity to buy lower-priced generic doxycycline delayed-

release capsules. On the other hand, a denial of a permanent injunction, which would allow Mylan to market a generic Oracea®, would increase competition, making rosacea treatment more accessible by lowering the cost to the patient. This would likely result in increased output (additional prescriptions) associated with sales to new rosacea drug users who would not have otherwise tried Oracea® due to its higher price point.

25. In contrast, a permanent injunction would provide a disincentive to Mylan and other generic suppliers to develop low-priced pharmaceuticals that compete with branded drugs.

26. Recognizing these considerations, I have concluded that the public interest would be served by investigating other remedy options beyond a permanent injunction in this matter. Such an effort should preserve the incentives to innovate under the patent system while also encouraging firms, like Mylan, to challenge problematic patents (such as invalid patents) or to develop alternative approaches that do not violate valid patents.

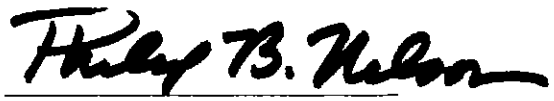
27. I have also concluded that such an investigation is likely to identify remedies besides a permanent injunction that are more appropriate, given the circumstances. In particular, with a more tailored compensation approach, it may be possible to take account of both the losses to consumers [redacted], as well as Galderma's valid intellectual property rights.

28. In the context of this case, a remedy, such as a licensing remedy that involves the payment of a royalty to Galderma, can have advantages over a permanent injunction. In particular, it can allow an efficient manufacturer/distributor of generic Oracea® to enter the market, providing competition that benefits consumers through lower prices. Moreover, [redacted], while also allowing Galderma to profit from any valid intellectual property that it owns.

29. In contrast, a permanent injunction without more will irreparably harm the public (consumers) because they will not be compensated for the lost opportunity to buy lower-priced generic doxycycline delayed-release capsules but for the preliminary injunction.

In addition, a permanent injunction will not preserve the incentives of Mylan and other generic suppliers to develop low-priced pharmaceuticals and challenge problematic patents but, rather, embrace and perpetuate the extraordinary (yet undeserved) benefits bestowed upon Galderma by virtue of the preliminary injunction.

I declare under penalty of perjury that the forgoing is true and correct.
Executed on September 2, 2011 in Washington, DC.



Philip B. Nelson

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CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on September 9, 2011, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on September 9, 2011, the attached document was Electronically Mailed to the following person(s):

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